

IN THE CLAIMS: See Listing of Claims. This listing will replace all prior versions of claims in the application.

REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 4-6 are pending in the application. The Office raises rejections under 35 USC § 112, first and second paragraphs.

Claims 4-6 are rejected for lack of written description under 35 USC § 112, first paragraph. It is the position of the Office that the phrases "a condition associated with gastro-duodenal pain" and "a living animal body, including a human" are not supported by the description in the specification.

Claims 4-6 are further rejected for lack of enablement under 35 USC § 112, first paragraph. It is the position of the Office that the specification does not reasonably provide enablement for the treatment of the "plethora of conditions" associated with gastro-duodenal pain. The Office acknowledges that data from a clinical study are provided in the specification; however the Office states that the specification does not provide "a single example of the type of condition being treated" nor does it provide "examples of a condition associated with gastro-duodenal pain." It is the position of the Office that the patient population of the clinical study is not defined, and that it is unclear whether the study was done in humans or in animals. It is the further position of the Office that it is not clear whether the difference reported between treatment groups in the clinical study are significant.

Claims 4-6 are also rejected for indefiniteness under 35 USC § 112, second paragraph, based on the phrase "living animal body, including a human." It is the position of the Office that the phrase "including a human" in Claim 4 is indefinite because it represents a subgeneric phrase included within a generic phrase.

With the instant Amendment, Claim 4 has been amended to recite "a method for treating a patient afflicted with a condition selected from gastro-duodenal pain,

gastritis, and duodenitis, comprising administration of an amount of the strontium salt ... which is effective for treatment of the condition". Dependent Claims 5 and 6 have also been amended accordingly. The Applicants respectfully submit that there is literal support in the specification (at pages 2-3) for the term "patient" as well as for the terms "gastro-duodenal pain," "gastritis," and "duodenitis." Moreover, the instant specification discloses (at page 3) that various dosage amounts of strontium ranelate may be used. Therefore, the Applicants respectfully submit that the specification also provides support for "an amount which is effective for treatment of the condition." With respect to the indefiniteness rejection based on the phrase "a living animal body, including a human," the Applicants note that this phrase is no longer recited in the claims.

As noted above the conditions (i.e., gastro-duodenal pain, gastritis, and duodenitis) recited in the claims, as amended, are disclosed in the specification (at page 2). Moreover these conditions are disclosed to be encompassed by the term gastric pain (at page 2 of the specification). Thus, the Applicants respectfully submit that treatment of these conditions is enabled by the clinical data disclosed in the specification. Moreover, with respect to the Office allegation that the clinical data is not clear, the Applicants respectfully submit that the disclosed data certainly enable a claim to *treating a patient* and that the specification specifically states that gastric pain was **significantly** reduced in patients treated with strontium ranelate compared to patients treated with placebo. In other words, the difference of at least 30% between the treated group and the placebo group was statistically significant.

Thus, the Applicants respectfully submit that the instant claims, as amended, comply with both the written description and the enablement requirements under 35 USC § 112, first paragraph. Moreover, the indefiniteness rejection under 35 USC § 112, second paragraph, has also been obviated by the instant Amendment. Reconsideration and withdrawal of the rejections under 35 USC § 112, first and second paragraphs, is respectfully requested.

Finally, the Applicants note that the Examiner has not considered the International Search Report (ISR) and International Preliminary Examination Report (IPER) which

were included with the Information Disclosure Statement (IDS) submitted with the filing papers of the instant application. The Office states that these documents are not "published documents" and that, therefore, these documents do not have a publication date. The Applicants respectfully submit that the ISR and IPER are publicly available at the WIPO website, and that, therefore these documents are, in fact, "publications" in the international equivalent of the instant application. A copy of the listing of these references from the WIPO website is enclosed.

The Office has also not considered the EP 0415850 and EP 0813869 references, stating that copies of these references were not supplied with the IDS. With this Response, the Applicants provide copies of the EP 0415850 and EP 0813869 references as well as a new Form PTO-1449 listing English language equivalents of EP 0415850 and EP 0813869 (i.e., US Patent Nos. 5,128,367 and 5,856,356, respectively).

The Applicants respectfully request that the Office consider the references listed on the enclosed Form PTO-1449.

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Accordingly, entry of present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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Enclosure: Form PTO-1449 and Accompanying References; Reference Listing
from WIPO website; Listing of Claims; Check No. 76009 for One (1)
Month Extension Fee; and Postal Card Receipt

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